10

United States Court of Appeals for the Federal Circuit

NOVO NORDISK A/S AND NOVO NORDISK, INC.,
Plaintiffs-Appellants,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
AND SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellees.

2010-1001

Appeal from the United States District Court for the Eastern District of Michigan in Case No. 2:05-CV-40188, Judge Avern Cohn.

ON MOTION TO AFFIRM INJUNCTION OF THE DISTRICT COURT

Before RADER, *Chief Judge*, CLEVENGER and DYK *Circuit Judges*.

Order for the court filed by *Chief Judge* RADER. Opinion concurring in part and dissenting in part filed by *Circuit Judge* DYK.

RADER, *Chief Judge*.

Defendants-Appellees Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd. (collectively, "Caraco") move for summary affirmance of the injunction of the United States District Court for the Eastern District of Michigan pursuant to the Supreme Court decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), which reversed this court's judgment and remanded for further proceedings. Plaintiffs-Appellants Novo Nordisk A/S and Novo Nordisk, Inc. (collectively, "Novo") oppose. Caraco replies. For the reasons set forth below, this court affirms-in-part and modifies-in-part the District Court's injunction.

Novo argues that two issues remain to be resolved by this court on remand: (1) whether Novo's current use code is "correct"; and (2) whether the district court erred in issuing a mandatory injunction requiring Novo to reinstate its prior use code.

This court finds, in light of the admitted facts in this case, that the Supreme Court decision forecloses any argument that Novo's use code is "correct." The Court held that the counterclaim provided by 21 U.S.C. § 355(j)(5)(C)(ii)(I) can be used "to force correction of a use code that inaccurately describes the brand's patent as covering a particular method of using the drug in question." *Caraco*, 132 S. Ct. at 1675. The Food and Drug Administration ("FDA") has found Novo's current use code covers all three FDA-approved methods of using repaglinide. *Id.* at 1679; *see Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1363 (Fed. Cir. 2010). It is undisputed that Novo's U.S. Patent No. 6,677,358 ("'358 patent") claims only one of those three approved methods of use. *Caraco*, 132 S. Ct. at 1678-79; *Novo*, 601

F.3d at 1364. Thus, the current use code inaccurately describes Novo's patent as covering two FDA-approved methods of using repaglinide that the '358 patent admittedly does not cover. *Caraco*, 132 S. Ct. at 1688 (holding "Caraco may bring a counterclaim seeking to 'correct' Novo's use code 'on the ground that' the '358 patent 'does not claim . . . an approved method of using the drug'-*indeed, does not claim two*") (emphasis added) (quoting 21 U.S.C. § 355(j)(5)(C)(ii)(I)).

This court reviews a district court's grant of a permanent injunction and the scope of that injunction for abuse of discretion. *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 772 (Fed. Cir. 1993). The counterclaim statute provides that the remedy is "an order requiring the holder to correct or delete the patent information submitted by the holder" to the FDA. 21 U.S.C. § 355(j)(5)(C)(ii)(I). Damages are prohibited. *Id.* § 355(j)(5)(C)(ii)(III).

The District Court entered an injunction on September 25, 2009, which provided:

> Novo Nordisk is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(1)(bb) to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended form FDA 3542 *that reinstates its former U-546 listing* for Prandin and describes claim 4 of the '358 patent in section 4.2b as covering the "use of repaglinide in combination with metformin *to lower blood glucose*."

Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., No. 2:05-cv-40188, 2009 U.S. Dist. LEXIS 88551 (E.D. Mich., Sept. 25, 2009) (emphasis added).

The relevant FDA regulations make the branded company responsible for drafting appropriate use codes and submitting them to the FDA. *See* 21 C.F.R. § 314.53(c)(2)(ii)(P) (describing information to be submitted on FDA Form 3542 for each method-of-use patent). The company must certify under penalty of perjury "that this is an accurate and complete submission of patent information." FDA Form 3542, Part 6.1. In this context, an appropriate order granting relief under 21 U.S.C. § 355(j)(5)(C)(ii)(I) will give the branded company the opportunity to draft its own corrected use code.

The use code offered by the branded company must not "sweep more broadly than the patent." *Caraco*, 132 S. Ct. at 1683 n.7. Rather, the use code must accurately describe "the *patented* method of use"—i.e., the approved method of use claimed in the patent. 21 C.F.R. § 314.53(c)(2)(ii)(P)(3) (emphasis added). Here, the '358 patent claims "[a] method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin." '358 patent, claim 4. An appropriate use code therefore must be limited to use of "repaglinide in combination with metformin" to treat NIDDM.

This court holds that while the District Court was correct in issuing an injunction requiring correction of Novo's use code listing for the '358 patent, it abused its discretion in dictating the precise terms of the use code to be submitted on FDA Form 3542. To be clear, it is appropriate for district courts to construe the scope of the patent claims and provide clear limits on the appropriate scope of the corresponding use code. Within those limits, the branded company is given the opportunity to propose the specific language of the use code. Therefore, this court modifies the injunction as follows to permit Novo to

draft an appropriate use code in light of the guidance above. Contrary to the dissent's concerns, this holding does not give Novo unbounded discretion to propose a new overbroad use code. If the revised code offered is overbroad, the district court has the power to correct the error. Therefore,

IT IS ORDERED THAT:

> Novo Nordisk is hereby directed by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(1)(bb) to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended form FDA 3542 for Prandin that accurately describes the scope of claim 4 of the '358 patent in section 4.2b. The description shall be clearly limited to use of repaglinide in combination with metformin to treat non-insulin dependent diabetes mellitus.

FOR THE COURT

July 30, 2012
Date

/s/ Jan Horbaly
Jan Horbaly
Clerk

cc: Josh A. Krevitt, Esq.
James F. Hurst. Esq.

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DYK, *Circuit Judge*, concurring in part and dissenting in part.

I agree with the majority that under the Supreme Court's decision in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012), Novo's use code is not correct and Caraco is entitled to an injunction requiring Novo to correct its use code. I respectfully

dissent to the extent that the majority suggests the district court cannot order Caraco to adopt a compliant use code but only enjoin the use of an improper use code. As in the original decision, such an approach would read into the statute limitations that are not there.

The counterclaim provision entitles Caraco to the remedy of "an order requiring the [NDA] holder [i.e., Novo] to correct . . . the patent information [i.e., the use code]." 21 U.S.C. § 355(j)(5)(C)(ii)(I). On its face this provision appears to allow the district court to require a particular use code as a corrective measure. *See Webster's Third New International Dictionary* 511 (2002) (defining correct, in the year before the counterclaim provision's enactment, as "to make or set right," "remove the faults or errors from," or "alter or adjust so as to bring to some standard or required condition"). Traditionally, district courts have broad inherent authority to shape remedial injunctive orders. *See Lemon v. Kurtzman*, 411 U.S. 192, 200 (1973) ("In shaping equity decrees, the trial court is vested with broad discretionary power; appellate review is correspondingly narrow."); *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) (noting that district courts have inherent equitable authority to "mould each decree to the necessities of the particular case"). In particular, it is established that courts have authority to require specific affirmative acts through mandatory injunctions. *See California v. Am. Stores Co.*, 495 U.S. 271, 280-83 (1990) (holding that a statute entitling a party to "have injunctive relief" entitles parties to both prohibitory and mandatory injunctions under the "traditional principles of equity"); *Morrison v. Work*, 266 U.S. 481, 490 (1925) (stating that a mandatory injunction may be granted "in the exercise of a sound judicial discretion"); 1 Dan B. Dobbs, *Dobbs Law of Remedies* § 2.9 (2d ed. 1993).

"[T]he comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a *clear and valid legislative command.*" *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982) (emphasis added) (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946)); *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496 (2001). There is no "clear and valid legislative command" constraining the district court's broad discretionary power over the scope of the order requiring Novo to correct its use code. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). The majority may suggest that the district court's injunction was somehow improper because FDA regulations make the branded company responsible for initially proposing a use code,[1] but those regulations do not constrain the court's authority under the counterclaim provision to order a correction, and do not purport to do so. No statute or regulation says that a use code cannot be corrected by a court under the counterclaim provision. The use code information is simply the description of the scope of the patent. Courts routinely construe the scope of patent protection, so there is hardly anything unusual in the court's doing exactly the same thing in the context of the counterclaim provision.

Analogously, when the inventorship of a patent is challenged, 35 U.S.C. § 256 allows a court to "order correction of the patent." As with the FDA filings, the patent applicant is required to list the inventors in the first instance and to file an oath or declaration indicating that

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[1] Within 30 days of approval of a new drug, "the applicant shall submit FDA Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use." 21 C.F.R. § 314.53(c)(2)(ii). The required information on Form 3542 includes "[t]he description of the patented method of use" for each method-of-use patent. *Id.* § 314.52(c)(2)(ii)(P)(3).

the inventor list is correct. 37 C.F.R. § 1.63. We have never limited district courts' authority under this provision to ordering only general correction of an incorrect list of inventors, rather than directing who should be added or removed as a co-inventor. *See, e.g.*, *Bd. of Educ. ex rel. Bd. of Trs. of Fla. State Univ. v. Am. Bioscience, Inc.*, 333 F.3d 1330, 1342 (Fed. Cir. 2003) ("[W]e conclude that Soon-Shiong and Desai are coinventors with Tao of the compounds claimed in the '653 patent, but that Holton, Nadizadeh, and Yang are not.").

In its opinion in this case, the Supreme Court noted that "[a]n overbroad use code" like Novo's "throws a wrench into the FDA's ability to approve generic drugs," and that the counterclaim provision was enacted to remedy this problem. *Caraco*, 132 S. Ct. at 1684. Novo should not be permitted to throw in a new wrench each time one is removed by offering new overbroad use codes and forcing Caraco to seek correction of each one. Such an approach could potentially hamstring the district court by denying it the authority to state what the correct code is. This is a particularly easy case because the district court merely ordered the reinstatement of the use code originally proposed by Novo.

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